REMARKS

The Final Office Action mailed December 24, 2002 (hereinafter the Office Action), has been received and reviewed. Claims 1, 3 and 4 are presently pending in the application, and each of claims 1, 3, and 4 stand finally rejected in the Office Action. Applicants respectfully request amendment of claims 1, 3, and 4 as set forth herein. Further, Applicants respectfully request reconsideration of the application in light of such amendments, together with the remarks provided herein.

35 U.S.C. § 112 Rejections

Claims 1, 3, and 4 are rejected in the Office Action under 35 U.S.C. § 112, second paragraph. With regard to claims 1, 3, and 4, it is asserted in the Office Action that the term "up to 60%" includes 0% antiviral agent and it is unclear how an effective dose of antiviral agent can be administered without the drug. (*See,* Office Action, page 2). However, Applicants respectfully note that each of claims 1, 3, and 4, as they are proposed to be amended, recite dosage forms that include a drug formulation comprising an amount of antiviral drug. Therefore, applicants respectfully submit that the amendments contained herein overcome the rejection of claims 1, 3, and 4 under the second paragraph of Section 112, and Applicants respectfully request that the rejection of claims 1, 3, and 4 under Section 112 be withdrawn.

35 U.S.C. § 103(a) Obviousness Rejections

Each of pending claims 1, 3, and 4 stand rejected under 35 U.S.C. § 103(a) ("Section 103") as being unpatentable over Rudnic et al. (U.S. 5,952,004) in view of Eckenhoff et al. (U.S. 4,692,326) or Rudnic et al. in view of Eckenhoff et al. (U.S. 4,800,056). However, a rejection under Section 103(a) is improper and will be overturned unless a *prima facie* case of obviousness

is established against the rejected claims. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). Applicants respectfully submit that neither of the combinations of references cited in the Office Action provides evidence sufficient to properly establish the *prima facie* obviousness of any of claims 1, 3 or 4. Thus, Applicants respectfully request that the rejection of claims 1, 3 and 4 be withdrawn.

As is set forth in M.P.E.P. 706.02(j), a *prima facie* case of obviousness under Section 103 can not be established unless three criteria are met:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The examiner bears the burden of establishing these three criteria based on the prior art.

In the present case, Applicants respectfully submit that the combined teachings of the references cited against claims 1, 3 and 4 do not teach or suggest each of the claim limitations recited in the claims as they are amended. In particular, Applicants respectfully note that the combined teachings of the references cited in the Office Action do not teach or suggest a controlled release dosage that (1) includes a self-emulsifying antiviral formulation as recited in the rejected claims and (2) is configured to deliver the antiviral formulation as required by any one of the rejected claims. More specifically, Applicants respectfully submit that the combined teachings of the references cited against claims 1, 3 and 4 do not teach or suggest a controlled release dosage form that includes a liquid, self-emulsifying antiviral drug formulation, wherein an antiviral drug in solubilized form accounts for up to 60 wt% of the drug formulation. In addition, Applicants respectfully submit that the combined teachings of the references cited in the Office Action fail teach or suggest a dosage form that is configured to administer an antiviral formulation as defined in claims 1, 3 and 4 such that a therapeutically effective dose of antiviral

drug is delivered over at least 4, 12, or 24 hours at the rates specified in the rejected claims. Therefore, Applicants respectfully submit that the combined teachings of the references cited in the Office Action do not meet all the criteria necessary to establish the *prima facie* obviousness of claims 1, 3 and 4, and Applicants respectfully request that the rejection of these claims be withdrawn.

It is concluded in the Office Action that the combined teachings of the references cited against the claims establish the *prima facie* obviousness of dosage forms configured to provide the release rates recited in claims 1, 3, and 4. As support for this conclusion, it is asserted that the combined teachings of the cited references teach "one skilled in the art at the time of the invention that the release profile [of a dosage form] can be 'tailored' through adjustment of the ingredients in the capsules." (*See,* Office Action, page 4). In particular, it is asserted that both of the Eckenhoff et al. references teach that controlled release capsules providing sustained release of a drug formulation for periods of 1 hour to months can be prepared. (*See,* Office Action, page 3). However, Applicants respectfully submit that, even if true, such assertions do not establish the *prima facie* obviousness of the rejected claims.

Applicants respectfully emphasize that the *prima facie* obviousness of claims 1, 3, and 4 can not be established unless the combined teachings of the cited references teach or suggest all of the limitations recited in claims 1, 3, and 4. In this instance, therefore, in order to establish the *prima facie* obviousness of the rejected claims, the combined references must do more than teach or suggest that controlled release capsules providing sustained release of a drug formulation for periods of 1 hour to months can be prepared. Instead, the combined teachings of the cited references must teach or suggest a dosage form as recited in the rejected claims configured to provide the release rate profiles recited in the rejected claims. In order to establish the *prima facie* obviousness of claim 1, the combined teachings of the cited references must teach a dosage form comprising a liquid, self-emulsifying antiviral drug formulation as recited in claim 1, wherein the dosage form is configured to administer a therapeutically effective dose of said antiviral drug over a period of at least 4 hours after oral administration with no more than 30% by weight of said liquid, self-emulsifying antiviral drug formulation being released within

the first 1 hour after oral administration. In order to establish the *prima facie* obviousness of claim 3, the combined teachings of the cited references must teach a dosage form comprising a liquid, self-emulsifying antiviral drug formulation as recited in claim 3, wherein the dosage form is configured to administer a therapeutically effective dose of said antiviral drug over a period of at least 12 hours after oral administration with no more than 30% by weight of said liquid, self-emulsifying antiviral drug formulation being released within the first 4 hours after oral administration. And, in order to establish the *prima facie* obviousness of claim 4, the combined teachings of the cited references must teach a dosage form comprising a liquid, self-emulsifying antiviral drug formulation as recited in claim 4, wherein the dosage form is configured to administer a therapeutically effective dose of said antiviral drug over a period of 24 hours after oral administration with no more than 30% by weight of said liquid, self-emulsifying antiviral drug formulation being released within the first 12 hours after oral administration. Applicants respectfully submit that a simple teaching or suggestion that the release rate of controlled release capsules can be adjusted or tailored does not amount to a teaching or suggestion of the release rates recited in any of the rejected claims. Applicants further submit that the combined teachings of the references cited in the Office Action do not teach or suggest dosage forms as recited in any of claims 1, 3, and 4 that are configured to provide the release rates as defined in claims 1, 3, and 4. Therefore, Applicants respectfully emphasize that the combined teachings of the references cited in the Office Action do not teach establish the *prima facie* obviousness of any of the rejected claims.

Applicants further emphasize that, in order to establish the *prima facie* obviousness of claims 1, 3, and 4, there must be an established motivation, either in the references cited in the Office Action or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the teachings found in the cited references to achieve the subject matter recited in the rejected claims. In this instance, Applicants respectfully submit that there is no evidence provided in the Office Action that establishes a motivation to combine and modify the teachings of the references cited in the Office Action to arrive at the subject matter recited in the rejected claims. The combined teachings of the cited references make no indication of the

benefits to be achieved by dosage forms having each of the limitations recited in the rejected claims. In fact, the combined teachings of the references do not even teach or suggest each of the limitations recited in any of the pending claims. Moreover, Applicants respectfully submit that the Office Action fails to provide evidence beyond the cited references that works to establish the requisite motivation. Therefore, Applicants respectfully submit that the *prima facie* obviousness of claims 1, 3, and 4 has not been established, and Applicants request that the rejection of claims 1, 3, and 4 be withdrawn.

CONCLUSION

Applicants respectfully submit that entry of the requested amendments to claims 1, 3, and 4 is proper and should be carried out by the Examiner. In particular, Applicants respectfully submit that the amendments requested herein are supported by the as-filed specification and do not add any new matter to the application. Further, the amendments place the application in condition for allowance and do not raise new issues or require a further search. However, should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

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Respectfully submitted,

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